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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,407	02/05/2004	Dong-Soo Han	HAND3001/EM	2851

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BACON & THOMAS, PLLC
625 SLATERS LANE
FOURTH FLOOR
ALEXANDRIA, VA 22314

EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/771,407

Applicant(s)

HAN ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 5-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Response to restriction requirement filed 03/24/2006 is acknowledged. Applicant elected, without traverse, Group I, claims 1-4. Claims 5-7 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups. Cancellation of claims 5-7 is requested.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons.

A. The term "appearance frequency information" is vague and indefinite. Specification, p. 6, line 20, informs that

appearance frequency information of domain combination is obtained from sets of protein pairs known to interact with each other

However, it is not clear what kind of information is meant. Specification, p. 8, and claim 3 address calculation of "appearance frequency information" as appearance probability (AP). However, the term " $|dc(p)| \times |dc(q)|$ " in the equation 1 (p. 5 or claim 3) is merely multiplication of domain combinations within each of the two different proteins, p and q, and does not provide any "frequency" information.

Further, as the term "appearance frequency information" addresses "sets of protein pairs known to interact with each other" (see citation above), it is not clear how it is being applied to "non-interacting sets of protein pairs" as addressed in claim 1.

B. The term "interaction" used throughout the claims is vague and indefinite. It is not clear, what kind of interaction is meant, is it chemical, or enzymatic interaction, or forming hydrogen bonds, or hydrophobic interaction, etc?

Further, the meaning of interaction is not clear for the situation of proteins which are clearly identified in claim 1 as "non-interacting sets of protein pairs".

C. The term "designated" in claim 12 is not clear: how a domain combination being designated? The specification, although providing particular examples, does not provide a standard for ascertaining how a domain combination being designated, and

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one of ordinary skills in the art would not be reasonably appraised of the scope of the invention.

D. The term “each” as related to “each of interacting and non –interacting set of protein pairs” in claim 1 is not clear. What constitute “pairs” – a pair of “interacting” proteins, a pair of “non-interacting” proteins, a pair of “interacting” and “non-interacting” protein?

F. The term “interaction between two proteins” in claim 1b) is not clear: As in the previous paragraph, it is not clear which two proteins are meant.

G. The term “determining” with respect to “probability equation” in claim 1b) is not clear. Is it determining a new invention for each new pair of proteins or applying a known equation?

H. The phrase “equation applied to predict” in claims 1b) is not clear. Applied to what?

I. The claims are indefinite as they address constraints (8)-(20) without defining them.

MPEP 2173.05(s) requires:

Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table “is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience.” Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993)

Equations are viewed as the same type of information as Tables or Figure. The

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equations, and the parameters used therein, must be recited in the claims. Please provide definitions for the terms WF, $dc(p)$ and $dc(q)$ in the claims.

Claim Rejections - 35 U.S.C. § 101 and 112-1

The following is a quotation of the 35 U.S.C. § 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The claims are directed to method for statistically predicting an interaction probability between proteins but do not identify which “interaction” is being addressed. The only information used in the calculating steps is related to number of domains in each of the proteins, no information suggesting any type of interaction is included in calculations. No correlation to any known type of interactions is recited in the claims. The specification describes validation of the method as applied to yeast proteins (p. 12-17); however, again, only information used in the calculating steps is related to number of domains and no information suggesting any type of interaction is included in calculations. Note that in a similar approach Gomez et al (“Towards the prediction of

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complete protein - protein interaction networks". Pacific Symposium on Biocomputing 2002, Kauai, HI, United States, Jan.3-7, 2002 (2001), 413-424) use not only frequency information, but also combine it with information about functional interaction between known domains – even in this case, however, the authors acknowledge that due to limitation of the model it is extremely difficult to evaluate the true accuracy of the method and that a large number of errors is unavoidable (see p. 421). Further, the authors conclude that such type of predicting approach is severely limited by the use of previously defined domains and, while prone to errors when applied to a set of yeast proteins (i.e., same set used in the instant invention to validate the method, see p. 12) which mostly characterized by a single domain, will be even more problematic when applied to human proteins which are normally multidomain proteins. See p. 421, last paragraph.

A claim which merely recites estimating the effects of an independent variable on a dependent variable, where the variables are not identified, would not have a utility as further research would be required to determine what the effect is. As set forth in MPEP 2107, a "use" to do further research is not a utility under 35 USC 101. As applicant has failed to disclose enough information about the invention to make its usefulness immediately apparent to those familiar with the technological field of the invention, the claims lack utility. See MPEP 2107.01, and the analyses of utility in *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (1966) and *In re Ziegler*, 992 F.2d 1197, 26 USPQ2d 160U (Fed. Cir. 1993).

5. Claims 1-4 are also rejected under 35 U.S.C. §112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility, one skilled in the art would not know how to use the claimed invention.

Claim Rejections - 35 U.S.C. § 101

6. Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The following analysis of facts of this particular patent application follows the analysis suggested in the "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility"¹. Note that the text of the Guidelines is italicized.

To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways (Guidelines, p. 19):

- The claimed invention "transforms" an article or physical object to a different state or thing.*
- The claimed invention otherwise produces a useful, concrete and tangible result, based on the factors discussed below.*

In the instant case, the claimed invention does not "transform" an article or physical object to a different state or thing. This does not preclude the subject matter to be patentable as, for eligibility analysis, as

¹ Available at http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf

physical transformation “is not an invariable requirement, but merely one example of how a mathematical algorithm [or law of nature] may bring about a useful application.” AT&T, 172 F.3d at 1358-59, 50 USPQ2d at 1452. If the examiner determines that the claim does not entail the transformation of an article, then the examiner shall review the claim to determine if the claim provides a practical application that produces a useful, tangible and concrete result. In determining whether the claim is for a “practical application,” the focus is not on whether the steps taken to achieve a particular result are useful, tangible and concrete, but rather that the final result achieved by the claimed invention is “useful, tangible and concrete.” The claim must be examined to see if it includes anything more than a § 101 judicial exception. If the claim is directed to a practical application of the § 101 judicial exception producing a result tied to the physical world that does not preempt the judicial exception, then the claim meets the statutory requirement of 35 U.S.C. § 101. If the examiner does not find such a practical application, the examiner has determined that the claim is nonstatutory. (Guidelines, p. 20)

The question is thus whether the final result achieved by the claimed invention produces a result which satisfies all three criteria of being useful, and concrete, and tangible. In determining if the instant claims are useful, tangible, and concrete, the Examiner must determine each standard individually. For a claim to be “useful,” the claim must produce a result that is specific, substantial, and credible. For a claim to be “tangible,” the claim must set forth a practical application of the invention that produces a real-world result. For a claim to be “concrete,” the process must have a result that can be substantially repeatable or the process must substantially produce the same result again.

Furthermore, the useful, tangible, and concrete result must be recited in the claim itself, rather than addressed in specification.

(1) “USEFUL RESULT”

When the examiner has reason to believe that the claim is not for a practical application that produces a useful result, the claim should be rejected, thus requiring the applicant to distinguish the claim from the three § 101 judicial exceptions to patentable

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subject matter by specifically reciting in the claim the practical application. In such cases, statements in the specification describing a practical application may not be sufficient to satisfy the requirements for section 101 with respect to the claimed invention. Guidelines, p. 21.

As discussed in the utility rejection above, the invention does not satisfy the criteria of utility requirements as not being specific and substantial.

If the specification discloses a practical application of a § 101 judicial exception, but the claim is broader than the disclosure such that it does not require a practical application, then the claim must be rejected. Guidelines, p. 21:

In the instant case, the claims are directed to computational method of identifying interaction between proteins known in advance to be non-interacting. Such method is not directed to any practical application.

(2) "TANGIBLE RESULT" *The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. However, the tangible requirement does require that the claim must recite more than a § 101 judicial exception, in that the process claim must set forth a practical application of that § 101 judicial exception to produce a real-world result. The opposite meaning of "tangible" is "abstract."*

In the instant case, the claimed invention is directed to an abstract method which does not address any real interactions but merely carries computing steps using numbers of domains in proteins. The method arrives at the end at a "interaction probability value" which do not have a demonstrated real-world utility.

Further, the method as claimed may take entirely within the confines of a computer without any communication to the outside world as there is no outputting step claimed. Thus, the instant claims do not include any tangible result.

Thus, the final result achieved by the claimed invention produces a result which does not satisfy all three criteria of being useful, and concrete, and tangible.

Claim Rejections - 35 USC § 102 and 103.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1,2,4 are rejected under 35 U.S.C. 102(b) as anticipated by Gomez et al. ("Towards the prediction of complete protein - protein interaction networks". Pacific Symposium on Biocomputing 2002, Kauai, HI, United States, Jan.3-7, 2002 (2001), 413-424)²

Gomez et al teach a statistical method for the prediction of protein-protein interactions. The method is based on the treatment of proteins as collections of conserved domains, where each domain is responsible for a specific interaction with

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another domain. Frequency information with which specific domain-domain interactions occur within known interactions is determined. The frequency information is then used in a probability equation to assign probability to an arbitrary interaction between any two proteins with defined domains. Domain interaction data is complemented with information on the topology of a network and is incorporated into the model by assigning greater probabilities to networks displaying more biologically realistic topologies. See abstract and p. 415-416. Appearance frequency is presented as a matrix of probabilities. p. 418, section 4.1.

It is the Examiners position that all the elements of Applicant's invention with respect to the specified claims are instantly disclosed by the teaching of the reference cited above.

Conclusion.

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

² Alternatively, see Database Caplus, DN 139:97571

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Michael Borin, Ph.D.

Primary Examiner

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mlb